IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Eugene Bell and Tracy M. Sioussat Serial No.: 09/369,012 Filed: August 5, 1999 For: Bone Precursor Compositions Attorney Docket No.: TSS-017	Group Art Unit: 1653 Examiner: H. Robinson

Assistant Commissioner for Patents
Washington, D.C. 20231

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December 1, 2000
Date of Signature and of Mail Deposit

By: Nicholas P. Triano, III, Esq.
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AMENDMENT AND RESPONSE

Dear Sir:

This is in response to the Office Action mailed from the U.S. Patent and Trademark Office on September 18, 2000 (Paper No. 6). No extension of time is required at this time. Please amend the application as follows:

In the claims:

Please cancel claims 3, 10, 38, 41 and 47 without prejudice or disclaimer.

Please amend the following claims:

1. (Amended) A bone precursor composition, comprising a calcium cement and an injection vehicle [which is suitable for injection], wherein the calcium cement includes

monobasic calcium phosphate monohydrate and beta-tricalcium phosphate in a ratio by weight of about 1:2 to about 1:3.75.

4. (Amended) The composition of claim 1, wherein the calcium cement is in the form of granules with a diameter of [between] about 1 to 500 μm inclusive.

5. (Amended) The composition of claim 4, which [includes or] is conditioned with cells.

8. (Amended) The composition of claim 7, wherein the connective tissue cells are selected from the group consisting of ligament cells, [and] chondrocytes and tendon cells.

15. (Amended) The composition of claim 2, wherein said calcium cement comprises, by weight, [between] about 1 [and] to 5 percent calcium pyrophosphate, [between] about 5 [and] to 15 percent alpha-calcium sulfate hemihydrate, [between] about 5 [and] to 25 percent monobasic calcium phosphate monohydrate and [between] about 55 [and] to 75 percent beta-tricalcium phosphate.

20. (Amended) The composition of claim 19, wherein the extracellular matrix particulates comprise [between] about 0.05 to 20 weight percent of the composition when dry.

22. (Amended) The composition of claim 21, wherein said pore-generating particles are selected from the group consisting of gelatin, [and] calcium sulfate, [or] and mixtures thereof.

23. (Amended) A bone precursor composite, comprising a calcium cement and a biopolymer structure, wherein the calcium cement includes monobasic calcium phosphate monohydrate and beta-tricalcium phosphate in a ratio by weight of about 1:2 to 1:3.75.

27. (Amended) The composite of claim 23 wherein the biopolymer structure [is a] are fiber or fibers.

28. (Amended) The composite of claim 23 wherein the biopolymer structure is a mat[t].

31. (Amended) The composite of claim 23, wherein the biopolymer foam [and[/or the calcium cement includes or] is conditioned with cells.

33. (Amended) A bone precursor composition, comprising a calcium cement; and acid or pepsin extracted collagen, wherein the calcium cement includes monobasic calcium phosphate monohydrate and beta-tricalcium phosphate in a ratio by weight of about 1:2 to 1:3.75.

37. (Amended) The composition of claim 34, wherein the collagen comprises [between] about 0.1 to 2.5 weight percent of the composition when dry.

39. (Amended) The composition of claim 33, wherein the calcium cement is in the form of granules with a diameter of [between] about 1 to 500 μm inclusive.

40. (Amended) A method for preparing an injectable bone precursor composition, comprising combining calcium pyrophosphate, alpha-calcium sulfate hemihydrate, monobasic calcium phosphate monohydrate and beta-tricalcium phosphate, such that an injectable bone precursor composition is prepared, wherein the ratio by weight of monobasic calcium phosphate monohydrate to beta-tricalcium phosphate is about 1:2.5 to 1:3.75.

42. (Amended) The method of claim 40, further comprising the step of producing the bone precursor composition as granules of reacted, hardened cement having a diameter of [between] about 1 to 500 μm inclusive.

44. (Amended) The method of claim 43, wherein the neutralizing solution is selected from the group consisting of 3-[cyclohexylamino]-1-propanesulfonic acid (CAPS), triethanolamine, N-tris[hydroxymethyl]methyl-2-aminoethanesulfonic acid (TES), tricine, N-2-hydroxyethyl]piperazine-N'-[2-ethanesulfonic acid] (HEPES), glycine, phosphate buffer solution, *bis* tris propane, N-tris[hydroxymethyl]methyl-3-aminopropane sulfonic acid (TAPS), 2-amino-2-methyl-1-propanol (AMP), and tris[hydroxymethyl]aminomethane (TRIS).

46. (Amended) A method for producing or repairing connective tissue in a subject, comprising administering an injectable bone precursor composition to the subject, wherein the injectable bone precursor composition comprises calcium pyrophosphate,

calcium sulfate hemihydrate, monobasic calcium phosphate monohydrate and beta-tricalcium phosphate, wherein the ratio by weight of monobasic calcium phosphate monohydrate to beta-tricalcium phosphate is about 1:2 to 1:3.75.

48. (Amended) The method of claim 46, wherein the bone precursor composition is in the form of granules with a diameter of [between] about 1 to 500 μm inclusive.

49. (Amended) The method of claim 46, wherein the bone precursor composition [includes or] is conditioned with cells.

53. (Amended) The method of claim 46, wherein the bone precursor composition further comprises a therapeutic [and/]or analgesic agent.

Please add new claim 57.

57. [New] The composite of claim 23, wherein the calcium cement is conditioned with cells.

REMARKS

Claims 1-56 were pending. Claims 3, 10, 38, 41 and 47 have been cancelled without prejudice or disclaimer. Claims 1, 4, 5, 8, 15, 20, 23, 23, 27, 28, 31, 33, 37, 39, 40, 42, 44, 46, 48, 49 and 53 have been amended. Claim 57 has been added. Claims 1, 2, 4-9, 11-37, 39, 40, 43-46, and 48-57 are currently pending. No new matter has been added.

Support for the amendments to claims 1, 33, 40, and 46 can be found, for example, in cancelled claim 3, 38, 41 and 47, respectively, and throughout the specification.

Support for the amendments to claim 23 can be found, for example, in the specification at page 3, lines 15-16.

Support for the amendments to claim 44, can be found, for example, in the specification at least at page 26, lines 23-28.

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
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CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION

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The undersigned, David Dove and Lewis H. Ferguson III, President and Secretary, respectively, of Tissue Engineering, Inc., a corporation organized and existing under the laws of the State of Delaware, DO HEREBY CERTIFY as follows:

1. The name of the corporation (hereinafter called the "Corporation") is Tissue Engineering, Inc. The Corporation was incorporated on May 31, 1991.

2. The Certificate of Incorporation of the Corporation is being amended to change its corporate name from "Tissue Engineering, Inc." to "TEI Biosciences Inc.". Accordingly, Section 1 of the Certificate of Incorporation of the Corporation is hereby amended to read in its entirety as follows:

"1. The name of the corporation is:

TEI Biosciences Inc."

3. The foregoing amendment to the Certificate of Incorporation of the Corporation was duly adopted by the Board of Directors and stockholders of the Corporation in accordance with the provisions of Sections 141, 228 and 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned, David Dove and Lewis H. Ferguson III, President and Secretary, respectively, of the Corporation, have signed this Certificate of Amendment of the Certificate of Incorporation as of this 6th day of September, 2000.

TISSUE ENGINEERING, INC.

By: _____
David Dove
President

By: _____
Lewis H. Ferguson III
Secretary